	<b>TRUSTABLE FOODS PRIVATE LIMITED, TAHLI WAL, UNA HIMACHAL PRADESH</b>		
	<b>STANDARD OPERATING PROCEDURE</b>	Document No.	TFPIL/SOP/MGMT/01
<b>PRODUCT RECALL / WITHDRAWAL</b>		Issue Date	01/05/2022
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## 1. PURPOSE

This Procedure will how to carry out a food recall through an efficient, rapid identification as well removal of unsafe food and food that violate the Act and Rules & Regulations made there under from the distribution chain and informing consumers (where necessary) of the presence of potentially hazardous food in the market and ensure that unsafe food are contained and destroyed or rendered safe.

## 2. SCOPE

This Procedure covers all products manufactured and dispatch by the site that are determined or prima facie considered unsafe.

## 3. DEFINITION

**SOP** – Standard Operating Procedure

**Stakeholder** – Concern Authority

**CCP** – Critical Control Point

**HOD** – Head of Department

**FSTL** – Food Safety Team Leader

**MRM** – Management Review Meeting

**Act** – Means the Food Safety and Standards Act, 2006

**Food Chain** – for the purpose of these regulations includes food involved in manufacture, processing, distribution, sale, import and export;

**Food Recall** – means the action to remove food from the market at any stage of the food chain, including that possessed by consumers.

**Food Recall Plan** – means the procedures and arrangements that a food business operator shall have in place to retrieve food and food products from the food chain if a problem arises.

**Food Under Recall** – means the specific lot or batch or code number of food product that has been determined by the Food Authority or the Commissioner of Food Safety of the State or Union territory or the Food Business Operator as not in compliance with the Act or rules or regulations made there under.

**Recall Alert** – means any alert issued to the public by the Chief Executive Officer, Food Safety and Standards Authority of India or the Commissioner of Food Safety of the State or Union territory or the Food Business Operator under intimation to Chief Executive Officer, Food Safety and Standards of India and the concerned Commissioner(s) of Food Safety of the State(s) about the food under recall.


**Traceability** – means the ability to follow the movement of a food article through specified stage(s) of its production, processing and distribution.

**Unsafe food** – means food as defined under clause (zz) of sub-section (1) of section 3 of the Act.

**Withdrawal** – A situation in which a manufacturer stops selling a particular product either permanently or for a period of time, usually because of food safety problem.

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#### 4. RESPONSIBILITY


FSTL / Manager QA	<ul style="list-style-type: none"> <li>Responsible for coordination to all stake holders during recall activities and record maintenance of reporting and systematic recall of products.</li> <li>Responsible for completing the evaluation and investigation of all reportable events in a time effective manner and follow up to stake holders.</li> </ul>
All HOD's and stake holders	<ul style="list-style-type: none"> <li>Responsible providing sufficient &amp; expedite data during recall / withdrawal to effectively implementing the procedure.</li> </ul>
Factory Head	<ul style="list-style-type: none"> <li>Responsible for recall initiation order supply chain and concerned site team.</li> <li>Responsible for ensuring recall / withdrawal process completion effectively.</li> <li>Responsible for action implementation to Food Safety Commissioner or authority on action taken to avoid or posed by the specific batch or lot code of food supplied.</li> <li>Responsible for removing the food from sale or distribution, when requested by the Commissioner of Food Safety of the State or Union territory or the Food Authority, as the case may be.</li> </ul>

#### 5. PROCEDURE

##### 5.1. INTIATION OF FOOD RECALL PROCESS:

- 5.1.1** The Site shall established "Recall Procedure" to effectively remove / withdraw affected products from circulation, in the shortest possible time, to safeguard consumers from possible hazardous effects and at the same time safeguard the company's good public image.
- 5.1.2** Site shall follow food recall procedure including complete process of recall, post-recall report, and follow-up action in order to ensure the effectiveness of the recall and prevent recurrence.
- 5.1.3** Managing Director shall initiate a recall process to fulfil the responsibility.
- 5.1.4** The recall process shall also be initiated as a result of reports or complaints referred to the Management from any stake holder and if Management determines that there is a need to recall.

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### 5.1.5 Complaint and Hazard Classification

#### 5.1.5.1 Complaint types

- **FOOD SAFETY:** Is a situation in which there is a reasonable probability that the use of, or exposure to a product will cause serious adverse or temporary adverse health consequences. This includes foreign material complaints that have resulted or could result in serious harm to the consumer. (Class I or II refer to Hazard Classification)
- **QUALITY:** Is a situation of “off” – colour, - texture, - intactness, cold burn, sun burn, packaging of grapes that will not cause a serious adverse or temporary adverse health consequence. This includes foreign material complaints that have not resulted in serious harm to the Customer. (Class III – refer to Hazard Classification)

#### 5.1.5.2 Hazard Classification and Definition

- **Class I**  
Associated with food safety measures and if Detection of a reportable disease (**outbreak of salmonella & E. Coli**) may necessitate a class I recall
- **CLASS II**  
Associated with Food safety measures and Class II recalls may be warranted if **cleaning chemical residue or inclusions of foreign objects like threads, metals, plastic, and glass particle**, which may cause tissue damage. Both Class II and Class III require notification at the customer, the local health authority.
- **CLASS III**  
A Passive or Class III recall is also known as a Product Withdrawal. It is usually quality related. Class III product withdrawal includes **improper packing, improper coding, damaged cartons, dirty & filthy cartons, insects and inadequate handling** of the product during transportation. For quality reasons, a plant will withdraw the product.


### 5.2. OPERATION OF FOOD RECALL SYSTEM:

- 5.2.1. The site shall maintain records for every product dispatched from site, which include the names and addresses of suppliers / customers, Name of food, date of purchase, date of delivery, batch code, SKU, brand name, date of manufacture, date of expiry or best before date, for a period of one year from best before date or the expiry date, as applicable.

- 5.2.2. All the above distribution information for retrieving should be completed within Three hours of initial contact to recall team by the Customer / Regulatory Bodies / In house event.

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- 5.2.3. When notification of a product recall or withdrawal is receiving from the Customer, Regulatory Bodies or from In-house Incident the Site QA Manager / FSTL shall record the information. And notify the information to recall team.
- 5.2.4. Site QA Manager shall submit information as applicable, to the concerned Authority immediately but not exceeding twenty-four hours from the time it comes to his notice that such food requires recall in accordance with the provisions of these regulations and initiate the recall exercise, such information alert(s) may be sent by quickest means of communication including fax, e-mail, and speed post.
- 5.2.5. The Managing Director shall give orders to stop distribution of food under recall and also stop its production if necessary, without waiting for any instructions from the Food Authority of India to ensure that consumer safety is not compromised and shall contact everyone from the raw material vendor to the final consumer of the affected food by written communication, phone, e-mail, fax, or a combination thereof, notify the suppliers and any other relevant retailer or trade association and immediately identify all required product details along with any additional details which would facilitate speedy identification and recall.

### **5.3. RECALL PLAN:**


5.3.1 A recall plan shall establish at site to demonstrate any recall of product in such a manner.

- i) Initiation of food recall procedure
- ii) Operation of food recall system
- iii) Food recall plan
- iv) Recall communication
- v) Recall status report
- vi) Food recovery
- vii) Post recall report
- viii) Termination of recall
- ix) Follow up action

- 5.3.2 A withdrawal process shall be initiated if the products that have left the control of the organization and are subsequently reported to be unsafe and pose potential risk to the consumers or quality of products deviates from as per specified.
- 5.3.3 For this a well-knit communication network shall exist in the organization to cover important dispatch / sales segments through which implicated product can be reached expeditiously and can be kept off the customer / consumer interface.
- 5.3.4 Site should nominate Recall management team who will be responsible to take corrective action during product recall / withdrawal. Site Recall Team should be updated yearly or when any change.

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- 5.3.5 If the product is found to be unsafe, action should be initiated for withdrawal and following levels of notifications are advised:
- Within the organization
  - Regulatory authorities
  - Distribution Chain (Customer / Consumer)
  - Public warning
- 5.3.6 In the event a reported unsafe product, the organization will start collecting following information on the product implicated:
- Product name
  - Product description
  - Batch codes involved
  - Quantity of product implicated
  - Distribution details
  - Nature of the hazard

#### **5.4. RECALL COMMUNICATION**


- 5.4.1. The Managing Director initiating a food recall shall promptly inform customer, distributors / Retailers in the food chain including consumers about the recall.
- 5.4.2. Such recall communication shall be through written communication, phone, e-mail, fax, print media, electronic media, (TV or Radio or Internet or Combination) or a combination thereof and in case of written communication it shall be conspicuously marked "Food recall". The communication also be marked "urgent" and telephone calls or other personal communication shall be confirmed by one of the above methods and documented in an appropriate manner. The communication shall be in the form of 'Food Recall Notice' and shall contain the following information, namely:-

- (a) Name of the Manufacturer who recalling the food;
- (b) Name of the food, brand name, pack size, batch code number, date of manufacture, used by date or best before date;
- (c) The contamination or violation in the food or reason for such recall;
- (d) "Do not consume message";
- (e) Health warning and action;
- (f) The places or outlets / retailers where the food is found;
- (g) The action to be taken by the consumer;
- (h) Contact number for queries.

5.4.3. The site QA Manager shall respond to queries if any from the stake holders, Customers Party & Food Safety and Standards Authority of India within twenty-four hours of the receipt of the query. However detailed data, if required, may be submitted subsequently.

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## **5.5. FOOD RECOVERY:**


- 5.5.1. FSTL shall inform to sales / distribution system to locate & freeze the stocks and prevent redistribution.
- 5.5.2. Recall Coordinator / FSTL shall be locate the entire unused and used recalled product and will be documented.
- 5.5.3. Communication with customers (mail / fax or other means) should be maintained until the end of the Recall.
- 5.5.4. Recall Coordinator segregates the recalled product in a designated area of the food service operation.
- 5.5.5. The site shall store the recovered food in an area which is separated from any other food and is identified by a label plate including prominently "**RECALLED PRODUCT NOT FIT FOR HUMAN CONSUMPTION**".
- 5.5.6. The site shall maintain accurate records of the recovered food including their batch code, pack size, brand name, Date of manufacture, Date of expiry, best before date, and all related data, Proper recording system shall be available to ensure that recalled food is retrieved and its details are recorded.
- 5.5.7. Arranging for recovered stocks to be reprocessed or destroyed (in environment friendly manner) under QA supervision.
- 5.5.8. The site shall correct or re-process the recovered food, if permitted by Food Authority /customers. In all above case Site QA shall ensure disposal of such food in consultation with the stake holders / Food Authority and complete record of the disposal of such product shall be maintained.

5.5.9. Site Recall team shall ensure proper accounting of such stocks and mass balancing shall be 100%.

## **5.6. POST-RECALL REPORT:**

- 5.6.1. Site QA Manager submits a post-recall report to stake holders & Food, after completion of the recall process so as to enable the assessment of adherence to the recall procedures.
- 5.6.2. The Recall Coordinator / FSTL and Recall Team make a decision on the corrective action to be taken, and on how to prevent a Product Recall of this nature in the future (i.e. investigate / audit).
- 5.6.3. Recall Team determines effectiveness and efficiency of recall and outline any corrective actions required and implemented for future record.
- 5.6.4. Recall Coordinator writes a final report detailing all gathered information, volume of product recovered and volume unaccounted for. The report, in addition to any corrective actions taken for future recalls is recorded.
- 5.6.5. The cause, extent and result of a withdrawal shall be recorded and reported to top management and review in MRM.
- 5.6.6. Though There is no incident of unsafe food reported so far, the system designed must be tested for its effectiveness by mock recall once in a year.

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## **5.7. TERMINATION OF A RECALL:**

- 5.7.1. After confirmation from Managing Director, site Quality Manager shall communication to all stake holders about termination of recall by submitting a recall termination request form along with recall status report or post-recall report certifying that the recall was effective. The request shall be made in the form specified in **Schedule-III FSSAI**.
- 5.7.2. A recall shall be terminated when the stake holders determines that it is reasonable to believe that that the food under recall has been removed and / or disposed of in an appropriate manner and that steps have been taken to ensure that such incidents do not occur. Once after confirmation from stake holders / customers / regulatory authority, operation is resume normal operations thereafter.

## **5.8. FOLLOW-UP ACTION**

- 5.8.1. The Site Quality Manager shall provide the information to stake holders and regulatory authority with a report as soon a recall is completed, in any case not later than thirty days after completion of a recall, covering the following information, normally:-



- The circumstances leading to the recall.
- The action taken by site including details publicity.
- The extent of distribution of the relevant batch in the country and overseas.
- The results of the recall (quantity of stock returned, corrected, outstanding etc.).
- The proposed method of disposal or otherwise of recalled stock with record of destruction and / or correction, and.
- The action proposed to be implemented in future to prevent a recurrence of the problem.


## **6. ANNEXTURE**

- Product Recall Handling Team (TFPIL/MGMT/05/FR-01)
- Food Recall Information (TFPIL/MGMT/05/FR-02)
- Food Recall Status Report (TFPIL/MGMT/05/FR-03)
- Food Recall Termination Request (TFPIL/MGMT/05/FR-04)

## **7. REFERENCE**

The Gazette of India - Ministry of Health and Family Welfare (**FSSAI**)  
 SOP-Material Identification and Traceability TFPIL/SOP/MGMT/01  
 SOP Product Incident Reporting & Management-TFPIL/SOP/MGMT/02  
 SOP-Handling Customer Complaint - TFPIL/SOP/MGMT/07  
 SOP-Foreign Object Control - TFPIL/SOP/QA/05  
 SOP-Handling of Nonconforming and Potentially Unsafe Product - TFPIL/SOP/QA/04

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**Date:**

### **DETAILS OF CONTACT PERSONS IN CASE OF RECALL**

S.N O.	NAME OF PERSON	DESIGNATION	MAIL ID	MOB. NO.




	Team Member			
	Team Member			
	Team Member			
	Team Member			
	Team Member			
<b>Contact persons of external (Regulatory) bodies:-</b>				

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#### **Food Recall Information**

<b>S.N o.</b>	<b>Subject</b>	<b>Particulars</b>
1	Name and address of the Company	
2	Name, Contact Details of Organization Nominee	

3	Identify of the implicated food	(a)	Name of the food	
		(b)	Brand Name	
		(c)	Date of Manufacturing	
		(d)	Quantity of food affected	
		(e)	Batch / Lot / Code number	
		(f)	FSSAI License / Registration number with a company	
4	Reason for Recall			
5	Date and circumstances under which need for food recall was discovered			
6	Nature of violation of the provisions of the Act. Rules or Regulations made there under			
7	Sourced of Information & Address / Contact Detail:			
8	Analysis Result			
9	Total quantity Produced			
10	Duration of food business for this product			
11	Quantity of implicated product sold by company / individual in the food chain with documentary proof.			
12	Mode of Recall communication			
13	Action taken			
14	Remark			

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PRODUCT RECALL STATUS REPORT			

### **FOOD RECALL STATUS REPORT**

To,  
Food Authority's Reference number for recall \_\_\_\_\_ Date: \_\_\_\_\_

S.N o.	Subject	Particulars
1	Name of the food	

2	Name of the company	
3	Brand Name:	
4	Batch / Lot / Code Number:	
5	Date of Mfg / Packaging (PKD):	
6	Phone:	
7	Email Address:	


**Attention CEO, FSSAI / Commissioner of Food Safety of the State or Union territory**  
 I, \_\_\_\_\_, the authorized representative of .....(Name of the company) \_\_\_\_\_ hereby submit  
 the following Recall Status Report regarding the above-listed food:

**1. Quantity related details of the implicated product before recall initiation:**

S.No.	Subject	Particulars
(a)	Total quantity of food manufactured:	
(b)	Total Dispatch / Distributed Units	
(c)	Total quantity of food to be recalled	
(d)	Details in case quantity in row (a) and (c) are different, (reason thereof)	

**2. Communication:**

S.No.	Subject	Particulars
(a)	Total number & destination affected	
(b)	Number of destination notified	
(c)	Method of notification	

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**3. Destination Party (Customer) response:**

S.No.	Subject	Particulars			
(a)	Total number of destination				

	party responding				
(b)	Total number of destination party not responding				
(c)	Total quantity of food dispatched to No responding destination party				
(d)	Number of packaged units and its quantity sold to and returned by each Responding destination party	Sold		Returned	
		Number	Quantity	Number	Quantity
(i)	Destination Party:				
(ii)	Destination Party:				
(iii)	Destination Party:				
	Total				

Quantity of implicated product accounted for (Total amount in custody of firm, including that recalled expressed as percentage of total implicated):

#### 4. Effectiveness Checks:

S.N o.	Subject	Particulars
(a)	Total number required:	
(b)	Total number completed:	
(c)	Completion date:	


5. Estimated Recall Completion Date: \_\_\_\_\_

6. Proposed method of disposal of recovered stock / record of destruction:

7. Actions proposed to avoid recurrence in future, If available at this point.

Yours sincerely

Authorized Sign & Date  
Managing Director  
Company Stamp

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#### FOOD RECALL TERMINATION REQUEST

Date: \_\_\_\_\_

To,  
The CEO, Food Authority \_\_\_\_\_  
Food Authority's Reference No. For Recall: \_\_\_\_\_  
Company Name & Licences No. & Registration No. \_\_\_\_\_  
Product Brand : \_\_\_\_\_  
Product Name: \_\_\_\_\_  
Lot No. \_\_\_\_\_ Batch No. \_\_\_\_\_ Manufacturing Date / Packaging Date \_\_\_\_\_  
Best before / Expiry date \_\_\_\_\_  
Food Authority Contact Person: \_\_\_\_\_ Phone: \_\_\_\_\_ Email \_\_\_\_\_  
\_\_\_\_\_

**Ref: Request for Recall Termination**  
**Attention CEO, FSSAI / Commissioner of Food Safety of the State or Union territory**

\_\_\_\_\_ the authorized representative of .....(Name of the Company) state that the company has initiated a recall of the above-listed product / product on \_\_\_\_\_ (date) \_\_\_\_\_ that extended to the \_\_\_\_\_ level. Proper communications were made by phone, fax, email, mail and personal visit, and records of these communications have been provided to your offices which are annexed along.

**Recall Status Summery Report:**

**Proposed action plan to avoid reoccurrence:**

Signature & Date  
(Recall Coordinator)

Authorized Sign. & date  
(Managing Director)  
Company Stamp